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(HL)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/981,665	11/05/97	CIPKOWSKI	S 3000

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HM22/0913

EXAMINER

GRUN, J

ART UNIT	PAPER NUMBER
1641	11

DATE MAILED: 09/13/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No. <b>08/981,665</b>	Applicant(s) <b>CIPKOWSKI</b>
Examiner <b>James L. Grun, Ph.D.</b>	Group Art Unit <b>1641</b>

Responsive to communication(s) filed on 5 May 1999.

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

Claim(s) 16-19 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 16-19 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- Notice of References Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The amendment filed 05 May 1999 is acknowledged and has been entered.

Claims 16-19 are newly added. Claims 1-15 have been cancelled. Claims 16-19 remain in the case. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16-19 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over Sun et al (US 5,238,652) in view of Boger et al (US 4,518,565), either of Davis (US 5,119,830) or Lee-Own et al (US 5,500,375), and any of Huang et al (US 5,712,172) or Norell (US 5,441,698) for reasons of record in the prior rejection of the similar subject matter of claims 5-15. As set forth, it would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have supported the test strips of Sun et al on any known and conventional alternative support, such as those taught by Boger et al or Huang et al, with the expectation that a known support would perform its desired support function. It would have been further obvious to have provided the support as foldable (Boger et al; Norell) or comprised of multiple layers (Boger et al; Huang et al; Lee-Own et al; Sun et al), and as having various slots for test strip alignment (Boger et al) or windows for sample application or viewing (Boger et al; Huang et al; Lee-Own et al; Sun et al; Norell), as is conventional for such supports as taught by the references. It would have

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been further obvious to one of ordinary skill in the art at the time the instant invention was made to have provided the multiple membrane strip device of Sun et al, as modified, in the size and shape of a card because one would have been motivated to provide such a size and shape to the device to facilitate insertion, as suggested by the dip and read mode of operation taught in Boger et al, or incorporation of the device into a urine collection vessel either of conventional design as disclosed in Lee-Own et al or of a design such as that of Davis.

Applicant's arguments filed 05 May 1999 have been fully considered but they are not deemed to be persuasive.

In response to Applicant's arguments that there are no specific suggestions to combine the references, the Examiner recognizes that references cannot be arbitrarily combined and that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Nomiya*, 184 USPQ 607 (CCPA 1975); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). However, there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. *In re McLaughlin*, 170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. *In re Bozek*, 163 USPQ 545 (CCPA 1969). In this case, for the

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reasons of record, ample motivations to substitute a known and conventional holder having slots and windows, such as that taught by Boger et al also taken in view of other conventional elements in the manufacture of such holders taught by the other cited references, for supporting the drug of abuse test strips of Sun et al have been provided.

In response to Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Arguments against individual aspects of the references which were not relied upon in the rejection and which do not serve to teach away from the invention as a whole, such as particular structural elements of the holders of Sun et al or Lee-Own et al or Norell, were not found persuasive.

Applicant urges that Boger et al only teach a test strip holder wherein the "handle" of a test strip therein extends from the top of the holder. This is not found persuasive in view of the previously cited teaching that the holder can be made long enough to accommodate the strips in their entirety (column 4). Applicant's assertion that removal of the test strips for measurement is required by Boger et al was not found persuasive because the reference clearly teaches a holder in which openings are provided for sample application and for taking assay measurements in a photometric apparatus, if desired, on the multiple test strips preloaded in the holder. Moreover, the holder may be disposable and/or used for long term storage after use in testing, embodiments which would clearly be inconsistent with Applicant's arguments.

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Applicant urges that Huang et al only teach the test strips as used in the instant invention. This is not found persuasive in view of the laminated holder taught in the reference.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (703) 308-3980. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, James C. Housel, SPE, can be reached on (703) 308-4027. The fax phone numbers for official communications to Group 1640 are (703) 305-3014 or (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*JL*  
James L. Grun, Ph.D.  
September 8, 1999

*Christopher L. Chin*  
CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800 / 641